TITLE OF INVENTION

Optical Switching System for Catheter-based Analysis and Treatment

CROSS-REFERENCE TO RELATED APPLICATIONS

Not Applicable.

STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT

Not Applicable.

BACKGROUND OF THE INVENTION

1. Field of Invention

[0001] This invention pertains to apparatus for switching signals, lambdas, or bandgaps of optical spectrum in a catheter. More particularly, this invention pertains to selectively applying a plurality of optical signals to a optical fiber in a catheter and processing the optical signals returned from the catheter.

2. Description of the Related Art

[0002] During the past twenty years, the use of catheters to enter, diagnose, and treat diseases and malfunctions of the blood vessels and other vessels has become commonplace. Catheters are widely employed to deliver stents to occluded blood vessels, as well as to position and deploy balloons to enlarge occluded blood vessels. Also, catheters are used in combination with excimer lasers for treating and removing plaque.

[0003] Unfortunately, medical professionals are unable to take advantage of the relatively non-invasive catheter in certain cases. For example, in the case of a totally occluded aortic or other vessel, it is difficult or impossible to safely insert and position a catheter due to the difficulty or impracticability of using X-RAY techniques to position the catheter. In approximately 330,000 cases per year, this results in open-heart surgery, which in addition to a long and painful recovery and high expense,

carries significant risks.

[0004] Similarly, the usefulness of catheters in treating and removing plaque is often limited. Recent findings indicate that nonstenotic, lipid rich coronary plaques, also called "vulnerable plaques" or "biological hot plaques" are exceptionally likely to cause the vast majority of fatal heart attacks. In other words, the majority of the approximately 1,300,000 heart attacks that will occur this year are caused by a soft plaque, for which there is not currently available a viable tool for identifying, diagnosing, or treating. While catheter-based excimer lasers have been proven to be effective at treating and removing soft plaques, their use has been limited by the practitioner's inability to see and control the position of the catheter before, during, and after using the excimer laser.

[0005] Various tests exist for identifying persons at risk of myocardial infarction. These persons are candidates for further evaluation and treatment. In such a case, an ideal treatment and system would allow for the use of multiple devices within a single catheter, therefore allowing several functions, some complementary, over the course of a single catheter insertion procedure, which would allow: a) the use of an interferometer capable of navigating the catheter through the blood vessels to allow the catheter to be moved through total occlusions as well as through the twists and turns of the blood vessels; b) the use of an interferometer that could use multiple wavelengths to differentiate among various materials in the optical path, including vulnerable plaque, calcified plaque, arterial walls, etc.; and c) the intermittent use of an excimer or other laser to ablate, vaporize, or otherwise destroy the plaque in the path of the catheter.

[0006] There are three primary instruments routinely used in catheter insertion procedures. First, Michelson interferometers of various types are used to differentiate between plaque and arterial walls, and to do so with physical resolution in the range of 10 microns. Michelson interferometers provide the ability to see and navigate through a total occlusion. Second, Diffuse Reflectance Near Infrared Spectroscopy (DRNIRS), often with regard to multiple wavelengths, is effective at differentiating and identifying a wide variety of substances, including hundreds of plasma constituents,

such as glucose, calcified plaque, vulnerable plaque, total protein, human metalloproteins, creatinine, uric acid, triglycerides, uric acid, urea, etc. DRNIRS interferometry provides the capability to detect and determine materials without actually contacting or touching them. The substances are distinguished by the characteristic absorption and reflectance of specific wavelengths of light, typically between 300 and 2200 nanometers. Third, excimer lasers typically use a very short pulse, less than 1 microsecond, normally about 100 nanoseconds, and could be operated together with both types of interferometry in duty cycles as high as hundreds of hertz.

[0007] Other devices for evaluating and treating arterial disease are known to those skilled in art. As with all optical devices, it is generally known to use either a single fiber or a bundle of fibers to transmit one or more optical signals. Often these devices are intended to improve the resolution and/or information available using the known navigation and diagnostic techniques and focus on improving a single technique. Examples of such uses are described in the following U.S. patents. U.S. Patent Number 5,217,456, issued to Narciso, Jr., discloses a catheter for ablation of a lesion. The rotating catheter has a bundle of optical fibers that are used to make fluorescence measurements to identify the radial position of the lesion. U.S. Patent Number 6,384,915, issued to Everett, et al., and U.S. Patent Number 6,175,669, issued to Colston, et al., disclose the use of a multiplexed reflectometer for performing Michelson interferometry. Both patents describe a system including a optical fiber set contained within the catheter. The optical fibers are connected to the illumination source via an optical switch, which sequentially cycles the output of the source through the optical fiber set to diagnose consecutive spatially-distinct regions of a lumen. U.S. Patent Number 6,463,313, issued to Winston, et al., describes a device having dual Michelson interferometers. The outputs are combined to produce a composite image thereby providing more complete information to the medical professional. U.S. Patent Number 6,501,551, issued to Tearney, et al., discloses the combination of two sources of differing wavelengths using wavelength division multiplexing. The combined signal is injected into a single optical fiber in the catheter. The reflections are separated by wavelengths and guided to separate detectors associated with a particular wavelength.

[0008] Devices combining some navigation or diagnostic element, such as a Michelson interferometer, with a treatment element, such as a excimer laser, are known to those skilled in the art. These devices are represented by the angioplasty systems such as the those described in U.S. Patent Number 5,275,594, issued to Baker, et al. and in U.S. Patent Number 6,463,313, Winston, et al. Both Baker, et al., and Winston, et al., disclose systems that use feedback from the diagnostic element to control the operation of the treatment element. U.S. Patent Number 6,389,307, issued to Abela, discloses a system having a lower power diagnostic laser and a high power treatment laser coupled to the same optical fiber. The operator activates the desired laser, preferably one at a time, to achieve a desired function.

[0009] An optical switching system for use with a catheter-based analysis and treatment instrument that facilitates a procedure that combines navigation, identification, and correction within the domain of insertion and operation during a single catheter experience or procedure would offer dramatic benefits to save lives and preclude coronary events. This procedure would be an effective, efficient, and safe method for treating a very dangerous condition, especially when compared to the options of performing no procedure or performing a bypass surgery.

BRIEF SUMMARY OF THE INVENTION

[0010] An apparatus and method for treatment of the arteries of the heart using optical switches to allow safe navigation of blood vessels with a catheter through the use of one or more interferometer systems and intermittent or concurrent treatment through the use of a treatment laser, precise insertion of a stent to cover the hot plaque, or other tool. The apparatus and method allows differentiation among arterial walls, calcified plaque, vulnerable plaque, such as Biological Hot Plaque, thin capped fibrous atheromas (TCFAs), and other forms and substance in blood vessels. The device and method is useful in the treatment of Atherosclerosis, Arteriosclerosis, and Thrombosis, the performance of Hemodialysis Access Maintenance, and the insertion of Transjugular Intrahepatic Portosystemic Shunts.

[0011] The apparatus allows multiple optical sources to be switched into one or

more optical fibers in the catheter. The return signal from the catheter is switched between multiple optical detectors, such as an interferometer, a spectrum analyzer, and a reflectometer. The use of optical switches allows the use of one or more interferometric systems in the same fiber, as well as using the switches to control a duty cycle that protects the optical source and detectors and other vulnerable or sensitive optical devices from harmful back reflections generated by the short but powerful pulses of an excimer, or other, laser or light source, or in the case that such devices are not in danger of being harmed by back reflection, switching through several interferometric light sources in order to determine geometry and composition in the path of the catheter.

[0012] The use of an optical switch provides the capability to sample multiple lambdas and/or bandwidth spectra through a fiber and from the loci of a single fiber end in the catheter into the loci of a single point on an artery wall quick enough to safely assure that all the sampling of lambdas or bandwidth spectra occurred in the same loci in the artery allowing an inference as to the composition at that loci on the artery wall, allowing to differentiate among artery wall, calcified plaque, hot plaque and other materials.

BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWINGS

[0013] The above-mentioned features of the invention will become more clearly understood from the following detailed description of the invention read together with the drawings in which:

Figure 1 illustrates one embodiment of an optical switching system for use with catheter-based analysis and treatment;

Figure 2 illustrates one embodiment of the catheter adapted for use with the present invention;

Figure 3 illustrates the catheter of the present invention in the environment of an artery;

Figure 4 illustrates an alternate embodiment of the optical switching system for use with catheter-based analysis and treatment incorporating a treatment laser;

Figure 5 illustrates an alternate embodiment of the optical switching system for use with catheter-based analysis and treatment adapted for using external optical sources and detectors;

Figure 6 illustrates an alternate embodiment of the optical switching system for use with catheter-based analysis and treatment adapted for using external optical sources and detectors and incorporating a treatment laser;

Figure 7 is a flow chart of one method of sequencing the source switch and detector switch in relation to the catheter switch; and

Figure 8 is a flow chart of an alternate method of sequencing the source switch and detector switch in relation to the catheter switch.

DETAILED DESCRIPTION OF THE INVENTION

[0014] An optical switching system for use with catheter-based analysis and treatment, or optical switching system, is shown and described. The use of an optical switching system allows the use of one or more interferometric systems in the same fiber, as well as using the optical switching system to control a duty cycle that protects the optical source and detectors and other vulnerable or sensitive optical devices from harmful back-reflections generated by the short pulses of a high-power light source, such as an excimer laser, or in the case that such devices are not in danger of being harmed by back reflection, switching through several interferometric light sources in order to determine geometry and composition in the path of the catheter.

[0015] The use of optical switches greatly aids in safely constructing and using a device for locating, identifying, and removing a blockage. First, an optical switch allows the use of multiple wavelengths and the insertion of these into one or more optical fibers by rapidly switching among the available wavelengths. It is important to note that while various types of interferometry may often be performed on a single type of fiber, for the most part they cannot be operated at the same time as they would interfere with the functionality and resolution of the various interferometers. For this reason, in the case where multiple interferometers are useful, the optical switch permits one or more interferometers to operate through the same optical fiber set. For example, the procedure can use Michelson interferometry for navigating through a total occlusion and use Diffuse Reflectance Near Infrared Spectroscopy (DRNIRS) for

differentiating between blood, water, vulnerable plaque, calcified plaque, and other objects. Similarly, when using identifying interferometry, various wavelengths are required to identify different materials, such as calcium rich plaque, vulnerable plaque, blood, water, arterial walls, etc. Again, the optical switch allows the necessary wavelengths to be switched through the optical fibers. Second, an optical switch provides the ability to return the reflectances from the end of the catheter to multiple interferometry devices. Third, an optical switch makes it possible to break the optical connection to both optical sources and optical detectors during the use and duty cycle of a high-power laser. By taking the optical sources and optical detectors off-line protects them from harmful and potentially destructive back reflections, to which such devices are exceptionally vulnerable.

[0016] Figure 1 illustrates one embodiment of a catheter-based analysis and treatment instrument incorporating an optical switching system in a according to the present invention. The medical apparatus includes a multi-wavelength illumination source **102**, often a bank of low coherence lasers, that is optically connected to a first optical switch **104**. The illumination source **102** is generally any coherent light source that can be used for medical imaging and that can be properly carried by an optical fiber. In one embodiment, each of the lasers in the illumination source **102** has a unique wavelength and generates a coherent light beam that is useful for navigation of a lumen and/or differentiation or identification of objects within the lumen. The first optical switch **104** allows selection of one of the lasers from the bank **102** to be directed through a catheter **108**. The first port **122** of a circulator **106**, which is optically connected to the first optical switch **104**, redirects the selected laser beam through a second port **124** into a second optical switch **110**. The second optical switch **110**, which is optically connected to the circulator **106**, sequentially cycles the selected laser beam through a plurality of optical fibers **130** routed through the catheter **108**. The reflections of the laser beam from the catheter **108** are fed back into the circulator **106** through the second port **124** and redirected through the third port **128** of the circulator **106** into a third optical switch **112**. The third optical switch **112** connects the reflections of the laser beams to various optical detectors **122**. In the illustrated embodiment, the third optical switch **112** is connected to an interferometer **114**, a spectrum analyzer **116**, and a

reflectometer **118**. A processing device **120** controls the switching operations for the first optical switch **104**, the second optical switch **110**, and the third optical switch **112**. In addition, the processing device **120** communicates with the optical detectors **122**.

[0017] As illustrated and described herein, the optical circulator **106** passes signals between successive ports in one direction. However, those skilled in the art will recognize that single direction signal paths can be achieved using other devices including optical switches. The bank of lasers **102** is presumed to have multiple sources; however, those skilled in the art will recognize that a single tunable laser or other tunable source capable of generating the desired wavelengths could be used. In such an arrangement, the single source subsumes the functions of the multiple sources and the first optical switch without departing from the spirit and scope of the present invention. Similarly, the optical detectors **122** is illustrated as including multiple devices performing differing functions. Those skilled in the art will recognize that the optical detectors may include only a single analysis device or single multi-function analysis device and would not require the third optical switch. In either event, such a substitution could easily be warranted by advances in the illumination source or the optical detectors or may merely reflect a medical apparatus performing fewer functions than the illustrated embodiment.

[0018] Figure 2 illustrates the construction of the catheter **108** in greater detail. The primary tube **202** of the catheter **108** defines a number of channels that carry or remove various fluids or route or carry other cables, wires, and implements. In the illustrated embodiment, the catheter **108** carries four optical fibers **204A, 204B, 204C, 204D** arranged at cardinal points in the cross-section of the catheter **108**. The catheter **108** defines a large channel **212** through which various implements, such as balloons or stents, can be inserted and manipulated. The catheter **108** also carries a guide wire **214**. In addition, the catheter **108** defines a channel through which various fluids can be introduced and removed, for example, to inflate an angioplasty balloon. Accordingly, the catheter of the present invention incorporates multiple optical fibers fed by an optical switch with other medically necessary and/or useful features; however, those skilled in the art will recognize that configuration and

features of the catheter depend upon the usage for which the catheter is designed.

[0019] Those skilled in the art will recognize that the number of optical fibers depends upon the desired field of vision and the image processing occurring at the analysis device and, therefore, that number can be varied without departing from the scope and spirit of the present invention. Similarly, the arrangement of the optical fibers depends both upon number and the desired field of vision. Typical, the optical fibers will be equidistantly spaced around the perimeter of the primary tube to provide the most complete field of vision; however, those skilled in the art will recognize other arrangements may be used without departing from the scope and spirit of the present invention.

[0020] Figure 3 is a cross-section showing the catheter **108** navigating through a blood vessel **300**. The dashed cones represent the upper field of view **302** and the lower field of view **304**. The left and right side fields of view are not depicted. In the illustrated embodiment, the blood vessel **300** includes a variety of objects which require navigation or identification. The objects include a bump **306**, such as a plaque deposit, a bifurcation **308** of the blood vessel, a turn **310** in the blood vessel, an aortic dissection **312** (or other similar damage to the blood vessel), and a closure or narrowing **314** of the blood vessel.

[0021] Figure 4 illustrates an alternate embodiment of a medical apparatus **400** incorporating an optical switching system in a catheter-based analysis and treatment instrument according to the present invention. The medical apparatus **400** includes a treatment laser **402**, such as an excimer laser or similar laser, used for evaporation or ablation of an arterial blockage, such as a plaque deposit. A separate optical fiber **404** in optical communication with the treatment laser **402** runs through the catheter **408**. The medical apparatus **400** also includes a shunt **406** that is connected to the optical path during the operation of the treatment laser **402**. The shunt **406** is a dead-end optical path where higher power reflectances from the treatment laser **402**, which return through the optical fiber **124**, are routed to prevent damage to the sensitive interferometry devices **122**.

[0022] Figure 5 illustrates yet another embodiment of the medical apparatus **500** adapted for optical navigation and optical identification in conjunction with non-optical treatments, such as stent insertion or angioplasty. This embodiment of the medical apparatus **500** includes a plurality of input ports **502** for receiving optical signals from external optical sources, and a plurality of output ports **504** for transmitting optical signals to external optical detectors (not shown). The input ports **502** are routed through an optical switch **506**. The input port optical switch **506** is optically connected to another optical switch **508** associated with a group of optical fibers **510** carried by a catheter **512**. The catheter optical switch **508** is also optically connected to a third optical switch **514** associated with the plurality of output ports **504**.

[0023] The three optical switches **506**, **508**, **514** are interfaced by an optical junction **516**. The primary function of the optical junction **516** is to route the optical signals to the appropriate destination. This generally means that source signals are routed into the catheter and the reflectances returning from the catheter are routed to the output ports. A secondary function of the optical junction **516** is to prevent optical signals from traveling to undesirable destinations. This generally means that the reflectances are prevented from reaching the input ports **502** and the source signals are prevented from directly reaching the output ports **504**. These two functions are realized by implementing the optical junction with an optical circulator; however those skilled in the art will recognize that the optical junction can be built from combinations of other optical components including splitters, multiplexers, demultiplexers, and switches without departing from the scope and spirit of the present invention.

[0024] A controller **518** coordinates the operation of the three optical switches **506**, **508**, **514** so that the reflectances of an input signal of a certain type or wavelength are directed to the appropriate detector for analysis. This is facilitated by software routines processed by the controller **518** and commands received from an optional user interface **520**. If required, the optical junction can also be placed under the control of the controller **518**.

[0025] Figure 6 illustrates still another embodiment of the medical apparatus **500** adapted for optical navigation, identification and treatment. This embodiment expands upon that shown in Figure 5 with the inclusion of a treatment laser **602** and another optical fiber **604** in the catheter **512** for carrying the high power bursts of the treatment laser **602**. The operation of the treatment laser **602** is coordinated in the system by the controller **520**. Generally, during the operation of the treatment laser **602**, any or all of the other optical switches are moved to a safe position to optically isolate the optical sources and detectors from potentially harmful back-reflections of the treatment laser **602**. The safe position could be any position if the optical circulator provides optical isolation or can be a special position which connects the optical fibers **510** of the catheter **512** to optical dead-ends.

[0026] It should be noted that while the illustrated embodiments of Figures 1, 4, 5, and 6 show all three optical used together, the use of a single source switch, a single detector switch, and the various sub-combinations of the three switches are also contemplated by the present invention.

[0027] Another feature of the present invention is the ability to control the routing of the optical sources through the catheter to obtain a full picture of the lumen. By sending the signal from each optical source through a selected group of the optical fibers in the catheter a more accurate picture of the lumen is obtained. Figure 7 is flow chart of the sequencing of the optical sources relative to the optical fibers in the catheter. First, the controller actuates the source switch **700** making a selected input port active so that signals from a desired source can be used. The controller also actuates the detector switch **704** making a selected output port active so that reflectances from the input signals are routed to the desired detector. A group of optical fibers is selected **706**. This selection can be static, i.e., the same every time, or exhibit variability based upon detected conditions or user control. It is common for the group to include each optical fiber; however, subsets of the optical fibers can be selected. Next, the controller actuates the catheter switch to select the active optical fiber **706**. This continues until each optical fiber in the group has been used **708**. Those skilled in the art will recognize the activation sequence of the optical fibers can be varied without departing from the scope and spirit of the present invention.

[0028] Figure 8 is a flowchart of a variation on the sequencing function shown and described in reference to Figure 7. In this variation, the active optical fiber in the catheter remains constant while the input ports and the corresponding output ports are rotated. First, the controller selects the active optical fiber in the catheter **800**. Next, the group of input ports associated with the desired sequence of input sources is selected **802**. This is followed by the selection the group of output ports associated with the desired optical detectors **804**. Note that the input sources and detectors need not follow a one-to-one correspondence, as the reflectances from a single input source may be used by multiple optical detectors. The controller actuates the source switch to cycle through the selected group of input ports **806**. The controller also actuates the detector switch to cycle through the selected group of output ports **808**. The source switch and detector switch actuation continues until all selections of the input port group and the output port group have been made active **810**.

[0029] Figure 9 illustrates a cross-section of an alternate embodiment of the catheter **900** utilizing a single optical fiber **906**. Some of the basic features of the catheter **900** are visible in Figure 9. The catheter **900** defines a large channel **902** through which various implements, such as balloons or stents, can be inserted and manipulated. The catheter **900** also carries a guide wire **904**. The optical fiber **906** is disposed proximate to the perimeter of the catheter **900**. In the illustrated embodiment, the optical fiber **906** has a 200 micron core, although, those skilled in the art will recognize that other core sizes can be used without departing from the scope and spirit of the present invention. It is desirable to minimize the amount of blood between the end of the optical fiber and the point of interest in the artery, i.e., the arterial wall and the artifacts thereon. Accordingly, in the illustrated embodiment, the optical fiber includes a mirrored surface **910** disposed at an angle approximating 45 degrees. The mirrored surface **910** causes the lambas to exit the optical fiber **906** at a roughly 90-degree angle through a window **908** in the wall of the catheter **908** and intersect the arterial wall. By rotating the catheter **906**, a full 360-degree view is obtained. Those skilled in the art will recognize that any number of optical fibers can be used without departing from the scope and spirit of the present invention.

[0030] The usefulness of the information obtained is largely dependent upon the

acquisition speed of the information. A rapid acquisition speed allows both navigation and identification information to be obtained about the same location in the artery. If the acquisition speed is to low, the navigation information and the identification information are not associated with the same location within the artery and do not provide a complete picture. Obviously, the switching speed is dependent upon the forward movement speed and/or the rotational speed of the catheter and the number of wavelengths required to obtain a complete picture. The present inventor has found that a switching speed in the range of 30 to 50 milliseconds provides a sufficient data acquisition speed for most applications, although other switching time ranges are acceptable. The optical switching system of the present invention is capable of operating at the necessary switching speed to obtain useful information.

[0031] Certain characteristics of the optical switching system are useful in providing an efficient implementation; however, those skilled in the art will recognize that these characteristics are intended to be exemplary and not limiting. In various embodiments, the optical switching system latches exhibits low optical loss, nominally less than 1 dB, and low port to port variability, nominally less than 0.5 dB. The optical switching system latches in all positions, making the switch stable, resistant to shock and vibration and unintentional switching. The optical switching system exhibits temperature Independent operation with regard to optical performance. The optical switching system exhibits low polarization dependent loss, nominally less than 0.2 dB. The optical switching system exhibits a switching time quicker than 100 milliseconds.

[0032] From the foregoing description, it will be recognized by those skilled in the art that a device and method for safely navigating blood vessels using a catheter has been provided. The device and method uses an optical switch to control the inputs and outputs of optical fibers set in a catheter. The device can differentiate among arterial walls, calcified plaque, vulnerable plaque (biological hot plaque and thin capped fibrous atheromas), and other forms and substances in blood vessels. The device is useful in the treatment of the arteries of the heart, Atherosclerosis, Arteriosclerosis, Thrombosis, for the performance of Hemodialysis Access Maintenance, and for the insertion of Transjugular Intrahepatic Portosystemic Shunts.

In addition, the device provides for the intermittent or concurrent use of a treatment laser, such as an excimer laser, or other treatment tool, such as a stent or an angioplasty balloon, in conjunction with one or more interferometer systems and devices by use of optical switches.

[0033] While the present invention has been illustrated by description of several embodiments and while the illustrative embodiments have been described in detail, it is not the intention of the applicant to restrict or in any way limit the scope of the appended claims to such detail. Additional advantages and modifications will readily appear to those skilled in the art. The invention in its broader aspects is therefore not limited to the specific details, representative apparatus and methods, and illustrative examples shown and described. Accordingly, departures may be made from such details without departing from the spirit or scope of applicant's general inventive concept.